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No. 94-87

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

ETHICON, INC.,

Petitioner,

—v.—

HELEN KIRWIN EISENMENGER, an incapacitated person, by VERONICA EISENMENGER, her Guardian and Conservator,

Respondent,

—and—

JAMES E. MUNGAS and MONTANA DEACONESS MEDICAL CENTER,

Cross-Respondents.

ON WRIT OF CERTIORARI TO THE
SUPREME COURT OF THE STATE OF MONTANA

MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE AND BRIEF AMICI CURIAE IN SUPPORT OF PETITIONER ETHICON, INC.

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Pursuant to Rule 37.2 of the Rules of this Court, American Cyanamid Co., Boots Pharmaceuticals, Bristol-Myers Squibb, CIBA-GEIGY Corporation, Hoffmann-LaRoche Inc., Pfizer Inc., the Pharmaceutical Research and Manufacturers of America, Rhone-Poulenc Rorer Inc., Schering-Plough Corporation, The Upjohn Co. and Warner-Lambert Company

respectfully move the Court for leave to file a brief *amici curiae*. Counsel for Respondent, Helen Eisenmenger, declined on August 10, 1994 to consent to filing; the petitioner has granted its consent.

Movant the Pharmaceutical Research and Manufacturers of America (PhRMA), is a voluntary, nonprofit association representing more than 100 research-intensive companies engaged in the discovery and development of prescription pharmaceutical products. Each year, PhRMA members invest more than $13 billion in research and development. These private research efforts are the source of virtually all new medicines developed in the United States. PhRMA member companies, together with the physicians who prescribe and the patients who use their products, have a keen interest in ensuring that product liability actions are decided fairly and with due regard to the Constitutional rights of the parties involved.

The other movants are all companies engaged in the manufacture and sale of prescription drugs and devices. Each has been sued in various courts throughout the United States by plaintiffs claiming to have been injured by defective medicines and other medical products. Many of these lawsuits involve defendants in addition to the drug or device manufacturer. Typically, these include the treating physician and hospital. Thus, like Ethicon, Inc. in the case below, the manufacturers are often faced with claims stemming from injuries that a plaintiff asserts have been caused by the fault of more than one party. Moreover, like Ethicon, are often faced with contention interrogatories, *i.e.*, discovery requests that require the answering party to identify and apply its liability contentions to known or discoverable facts.

Movants believe that the decision of the Montana Supreme Court upholding a default liability judgment against Ethicon for allegedly failing to provide complete information in response to selected contention interrogatories concerning negligence by its codefendants was wrongly decided. More importantly, movants believe that the decision represents a serious departure from the protections afforded to litigants under the Fifth and Fourteenth Amendments to the United States Constitution because it deprived Ethicon of its defenses without any warning or other procedural guarantee of due process. Contrary to the express requirement of *Insurance Corp. of Ireland, Ltd. v. Compagnie Des Bauxites De Guinee*, 456 U.S. 694, 705 (1982), dismissal of Ethicon's defenses was neither "just" nor supported by a presumption that Ethicon lacked support for its asserted defenses, many of which were independent of the contention information requested in the interrogatories. Movants believe that the attached brief of *amici curiae* will assist this Court in evaluating the issue raised in Ethicon's Petition for a Writ of Certiorari.

For the foregoing reasons, the motion of American Cyanamid Co., Boots Pharmaceuticals, Bristol-Myers Squibb, CIBA-GEIGY Corporation, Hoffmann-LaRoche Inc., Pfizer Inc., the Pharmaceutical Research and Manufacturers of America, Rhone-Poulenc Rorer, Inc., Schering-Plough Corporation, The Upjohn Co. and Warner-Lambert Company to file a brief *amici curiae* in support of Ethicon's Petition for a

Writ of Certiorari to the Supreme Court of the State of Montana should be granted.

Respectfully submitted,

/s/ J. Peter Coll, Jr.
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Cross-Respondents.

BRIEF OF AMICI CURIAE IN SUPPORT OF ETHICON, INC.'S PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF MONTANA

QUESTION PRESENTED

Whether, under the Fifth and Fourteenth Amendments to the United States Constitution, a court may, without warning, enter a default liability judgment against a party based

solely on the party's failure to disclose an opinion harbored by its expert, where the party could prevail at trial without eliciting that opinion and where the failure to disclose the opinion does not support a presumption that the party lacks meritorious defenses.

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INTEREST OF AMICI CURIAE

American Cyanamid Co., Boots Pharmaceuticals, Bristol-Myers Squibb, CIBA-GEIGY Corporation, Hoffmann-LaRoche Inc., Pfizer Inc., Rhone-Poulenc Rorer Inc., Schering-Plough Corporation, The Upjohn Co. and Warner-Lambert Company are all companies engaged in the manufacture and sale of prescription drugs and devices. Each is regularly sued in various courts throughout the United States by plaintiffs claiming to have been injured by defective medicines or other medical products. These amici are joined in this brief by the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA's membership is comprised of an even larger group of more than 100 pharmaceutical companies. Collectively, its member companies produce the vast majority of prescription medicines sold in the United States.

Amici share a general interest in safeguarding the due process rights of litigants. In addition, amici share a common belief that the decision below will further burden the litigation process by forcing drug and device manufacturers to adopt and advance unwanted litigation positions in cases where treating physicians are also named as defendants. In this case, Ethicon, Inc. was sanctioned because it did not reveal, in response to contention interrogatories, that its expert believed that plaintiff's surgeon had been negligent. There is no evidence that Ethicon intended to solicit this opinion from its expert at trial, and there is no claim that Ethicon failed to disclose relevant facts upon which the expert's opinion was based.

In the interrogatory responses for which Ethicon was sanctioned, Ethicon contended that the opening in plaintiff's

suture was caused, in part, by the surgical technique used to close the incision, and not by any defect in the suture itself. (A 198-200) In other words, Ethicon planned to argue that the suturing technique caused the injury, but it did not plan to assume the additional burden of proving that the use of this technique deviated from the standard of surgical care applicable to physicians practicing in the State of Montana. There are legitimate tactical and business reasons why a large, out-of-state manufacturing defendant, such as Ethicon, might choose not to contend that a local, codefendant physician that uses its product was negligent, even if the company knows that such an argument might be made and could be supported by expert testimony.

Amici believe that discovery sanctions are inappropriate if based on a defendant's failure to adopt or disclose an expert's opinion that the defendant does not intend to elicit at trial, particularly where the defendant can prevail on the merits without eliciting that opinion. In this case, for example, Ethicon could have prevailed solely by proving that its product, a suture, was not defective. It was not necessary for Ethicon to contend or prove that the defendant doctor's surgical technique was improper and that consequently the plaintiff's injuries were caused by his negligence. To deprive Ethicon of all its defenses in this circumstance punishes Ethicon for choosing not to pursue defenses that its expert may have believed, but which Ethicon itself was not obligated to adopt.

Amici do not endorse discovery abuse. If an expert's opinion is not properly disclosed in discovery, that opinion may be excluded from evidence at trial. But amici do not believe that drug and device manufacturers should be required to

contend that a given practice by a physician is negligent under local law, even if that opinion is harbored by the manufacturer's expert. In effect, Ethicon was required to adopt its expert's opinion as its own or lose all its defenses. The court effectively imposed this requirement on Ethicon by entering a liability judgment without warning and without any reason to think that Ethicon lacked meritorious defenses.

BACKGROUND AND FACTS

Not infrequently, when a plaintiff sues a manufacturer for injuries stemming from an allegedly defective medicine or medical device, the plaintiff also sues the treating physician. *See* L. Frumer and M. Friedman, *Products Liability* § 53.02[4] (1994) (encouraging joinder of manufacturer and physician). The claims asserted in such cases against a defendant doctor and a defendant manufacturer are different. In the case of the physician, plaintiffs typically claim there was negligence, *i.e.*, that the plaintiff's injury resulted from a course of treatment, employing a medicine or medical device, that deviated in some manner from the requisite standard of care.[1] The manufacturer, by contrast, is usually sued on a strict liability theory. Depending upon the type of strict liability asserted, this theory can be less onerous to prove than negligence, because it requires no showing of fault. *See* L. Frumer and M. Friedman,

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[1] This standard of care can vary depending upon the medical community in which the physician practices and the medical specialty in question. *See* Restatement (Second) of Torts, § 299A (1965). Under Montana law, physicians are subject to different standards of care depending upon (1) when the treatment occurred, (2) whether the practitioner is board certified as a specialist, and (3) the locality in which the physician practices. *Chapel v. Allison*, 241 Mont. 83, 785 P.2d 204 (Mont. 1990).

Products Liability, supra, § 1.06; Restatement (Second) of Torts, *supra,* § 402A; *Jackson v. Coast Paint and Lacquer Co.,* 499 F.2d 809, 812 (9th Cir. 1974) (Montana law). Regardless of fault, however, the plaintiff is required to prove that the product was defective and that the defect caused the plaintiff's injury. W. Page Keeton, et al., *Prosser and Keeton on The Law of Torts* §§ 41, 42 (5th Ed. 1984); Restatement (Second) of Torts, *supra,* § 430; *Young v. Flathead County,* 232 Mont. 274, 281-82, 757 P.2d 772, 777 (Mont. 1988); *Rost v. C.F.& I. Steel Corp.,* 189 Mont. 485, 616 P.2d 383, 386 (Mont. 1980). Absent proof that the defect in the product caused the injury in question, the manufacturer is not liable.

The presence of multiple defendants in the same case, each of whom may be subject to a different liability standard, influences the course of the litigation, including discovery. This is particularly true where, as here, the manufacturer asserts that its product was not defective and that something other than a defect in its product was the cause of the plaintiff's injuries. In some cases, the manufacturer may attribute plaintiff's injuries to negligence by the treating physician. *E.g., Meschino v. North American Drager, Inc.,* 841 F.2d 429 (1st Cir. 1988) (negligent use of medical device); *Bristol-Myers Co. v. Gonzales,* 561 S.W.2d 801 (Tex. 1978) (negligent method of administration by doctor). In other cases, the cause does not rise to the level of negligence. For example, in the typical case alleging that a prescription drug is defective because it is accompanied by inadequate warnings, proximate cause is negated by a demonstration that the physician prescribed the drug with full knowledge of its side effects. *See, e.g., Lindsay v. Ortho Pharmaceutical Corp.,* 637 F.2d 87, 92 (2d Cir. 1980) (New York law); *Stewart v. Janssen Pharmaceutica, Inc.,* 780

S.W.2d 910, 912 (Tex. Civ. App. 1989) (Texas law); *Mampe v. Ayerst Laboratories,* 548 A.2d 798, 803 (D.C. App. 1988) (District of Columbia law). Such conduct by the physician, while hardly negligent, is sufficient reason to conclude that the manufacturer's warning did not proximately cause the injury. *See also Plummer v. Lederle Laboratories,* 819 F.2d 349, 358-59 (2d Cir.), *cert. denied*, 484 U.S. 898 (1987) (California law) (allegedly inadequate warning not a proximate cause of plaintiff's injury where the physician knew product's risks but did not tell patient's parent).

In this case, Ethicon stopped short of contending that plaintiff's surgeon, Dr. James Mungas, was negligent. Instead, Ethicon's responses to Dr. Mungas' contention interrogatories disclosed an intent to argue that plaintiff's injuries were not caused by any defect in the Ethicon suture, but were attributable, in part, to the technique Dr. Mungas used to suture plaintiff's incision, *i.e.,* working continuously from one end of the incision to the other with a single suture. But the possibility that this suturing technique may have caused the incision to open does not necessarily mean that its use constituted negligence under the standard of care applicable to surgeons practicing in Montana. Indeed, plaintiff herself abandoned a claim of negligence against Dr. Mungas, despite knowledge that he used the continuous suture technique to close the incision, because plaintiff's experts, Dr. Frederick Hetzel and Dr. Paul Collier, took a position similar to Ethicon's. Neither claimed that Dr. Mungas was negligent. Significantly, Dr. Collier, a surgeon practicing in Pennsylvania, testified that he himself did not use the continuous suture technique employed by Dr. Mungas. Yet he did not testify that Dr. Mungas' technique deviated from the applicable standard of care. (A 185-87, 190)

Venturing beyond Ethicon's contentions, however, Ethicon's expert, Dr. Cornelious Olcott, testified that, in his opinion, Dr. Mungas was negligent. He did so at his deposition in response to questions posed by plaintiff's counsel. The plaintiff then moved for sanctions, and the trial court found that Ethicon had willfully abused the discovery process because its responses to plaintiff's contention interrogatories did not disclose Dr. Olcott's opinion regarding Dr. Mungas' surgical technique. (A 438) The trial court observed that Ethicon, through its counsel, had knowledge of Dr. Olcott's opinion when Ethicon answered the interrogatories. (A 436) Notably, the court did not find that Ethicon intended to solicit this opinion from Dr. Olcott at trial. Nor did it find that Ethicon contended that Dr. Mungas was negligent. Nevertheless, the court determined that Ethicon's failure to disclose Dr. Olcott's opinion in its interrogatory answers amounted to "knowing concealment." (A 437)

The trial court's Memorandum and Order recites a litany of contention interrogatories demanding that Ethicon state its contentions with respect to the etiology of plaintiff's injury. (A 418-33) In response to the earliest of these interrogatories Ethicon stated that it was unable to respond due to a lack of information, but indicated that it intended to "examine the etiology of plaintiff's cerebral vascular accident and may, depending upon the outcome of discovery, offer expert medical opinion on this subject." (A 421-28) Later, after the discovery was more fully developed, Ethicon attributed plaintiff's injury, in part, to "the surgical technique employed" during the operation. (A 198-200) In addition, Ethicon produced a "Dear Doctor" letter that was sent to surgeons prior to plaintiff's operation which cautioned that use of the continuous suture

technique employed by Dr. Mungas increased the risk that the suture could untie following surgery. (A 005)

The trial court held Ethicon responsible for plaintiff's decision to abandon her claim of negligence against Dr. Mungas, by finding that plaintiff would not have done so had she known of Dr. Olcott's opinion. (A 437) The trial court also blamed Ethicon for the court's decision to grant Dr. Mungas summary judgment on plaintiff's claim of *res ipsa loquitur*. (*Id.*) The possibility of precluding Dr. Olcott from testifying was apparently considered, but was rejected as insufficiently severe. (A 438) Instead, the court entered a liability judgment against Ethicon and proceeded to a trial on damages.

At the damages hearing, the court expressed misgivings about the sanction's severity, but it did not modify the sanction it had imposed. (A 309, 311) Despite the trial court's misgivings, the Montana Supreme Court upheld the default sanction based on the trial court's finding that Ethicon's responses were made in bad faith.

ARGUMENT

THE DECISION BELOW UNFAIRLY COERCES MANUFACTURERS OF MEDICINES AND MEDICAL PRODUCTS TO COMPLICATE THE LITIGATION PROCESS BY ADOPTING UNWANTED LITIGATION POSITIONS IN CASES INVOLVING TREATING PHYSICIANS

This Court has made it clear that use of the default sanction is constrained by the Due Process Clause of the U.S. Constitution because it deprives litigants of their opportunity to be heard. *Insurance Corp. of Ireland, Ltd. v. Compagnie des Bauxites De Guinee*, 456 U.S. 694 (1982), *Societe Internationale Pour Participations Industrielles Et Commerciales, S.A. v. Rogers*, 357 U.S. 197 (1958); *Hammond Packing Co. v. State of Arkansas*, 212 U.S. 322 (1909); *Hovey v. Elliott*, 167 U.S. 409 (1897). Most recently, these limits were described in *Insurance Corp. of Ireland, supra*, 456 U.S. at 707:

> Rule 37(b)(2) [of the Federal Rules of Civil Procedure] contains two standards–one general and one specific–that limit a district court's discretion. First, any sanction must be "just"; second, the sanction must be specifically related to the particular "claim" which was at issue in the order to provide discovery. While the latter requirement reflects the rule of *Hammond Packing, supra*, the former represents the

general due process restrictions on the court's discretion.[2]

National Hockey League v. Metropolitan Hockey Club, Inc., 427 U.S. 639 (1976) appears to address the first requirement—that the sanction be just. That case upheld dismissal as a sanction where the plaintiff had engaged in "flagrant bad faith" by failing, during a 17 month period, to answer interrogatories despite numerous warnings and an order from the court directing it to do so. *Id.* at 640-41. This Court held that, under the circumstances there presented, the trial court did not abuse its discretion by dismissing plaintiff's complaint. *Id.* at 643.[3]

The Montana Supreme Court upheld the entry of a default liability judgment based on the trial court's finding that Ethicon's failure to disclose Dr. Olcott's opinion constituted willful discovery abuse. But that finding rested on a false premise. The interrogatories to which Ethicon responded were contention interrogatories. Dr. Olcott's opinions were responsive to those interrogatories only to extent that Ethicon

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[2]The *Hammond Packing* limitation is itself a limitation imposed by the Due Process Clause. 212 U.S. at 351.

[3]As noted in Ethicon's Petition for a Writ of Certiorari, despite this Court's statement in *Insurance Corp. of Ireland, Ltd., supra,* that there are two requisites that must be satisfied in order to comport with the requirements of the Due Process Clause, some circuit courts have read *National Hockey League* to permit dismissal solely on the basis of bad faith. *E.g., Valentine v. Museum of Modern Art,* No. 93-9350, 1994 WL 324557 (2d Cir. July 5, 1994).

adopted them as contentions. Here, there was no finding that Ethicon contended that Dr. Mungas was negligent or that it needed to prove the doctor's negligence in order to prevail on the merits. In the absence of such findings, Ethicon cannot be said to have abused the discovery process, because it cannot be said to have misstated its contentions.

The contentions Ethicon did disclose—that the suture was not defective and that it opened due, in part, to the suturing technique used—provided sufficient grounds for a judgment in Ethicon's favor. Neither contention required Ethicon to prove that Dr. Mungas was negligent under Montana law. Indeed, plaintiff herself conceded that her injury could have occurred in the absence of negligence by the doctor. (A 182)

Adverse surgical results are not always, or even usually, caused by negligence. The "mere fact that an operation does not result in a favorable outcome does not establish—or even constitute evidence of—a deviation from the standard of care." *Campbell v. United States,* 904 F.2d 1188, 1192 (7th Cir. 1990). Moreover, medicine is not an exact science, and different physicians may appropriately use and advocate different techniques. For that reason, "differences in medical opinion are not inconsistent with due care." *Id.*, 904 F.2d at 1193. This is particularly so given that the applicable standard of care can vary depending on the practitioner, location and time of surgery. *Chapel v. Allison, supra.* Surely Dr. Olcott's opinion that Dr. Mungas' technique was negligent is an opinion upon which reasonable minds can differ. Ethicon was free to adopt or reject it. *See also MacGuiness v. United States,* 738 F. Supp. 566, 571 (D.D.C. 1990), *aff'd,* 927 F.2d 1258 (D.C. Cir. 1991) (no negligence despite use of surgical technique

described as "not preferred"); *Lindley v. Hamilton,* 883 F.2d 360, 363 (5th Cir. 1989) (alternate courses of treatment both met standard of care); *East v. United States,* 745 F. Supp. 1142, 1149 (D. Md. 1990) ("a doctor cannot be found liable simply because another doctor criticizes the care provided and would not have provided the same care").

The freedom to choose whether to assert physician negligence is important to amici generally. Because medicine is not an exact science, practitioners frequently disagree as to the best method to treat an illness or perform a given procedure. These disagreements do not imply negligence. There can and should be a proliferation of medical techniques and approaches. *See* Joseph E. Campbell, *Civil Liability for Investigational Drugs: Part II,* 42 Temple Law Quarterly 289, 311 (1969) (stressing importance of investigational techniques in furthering medical progress). Amici themselves frequently compete with one another to persuade physicians that one drug or device is better suited to a particular problem than another. But amici recognize that many approaches and techniques are valid, and none believe that a physician who chooses a competing product or uses a technique other than that recommended is for that reason guilty of malpractice.

Ethicon decided in this case not to contend that Dr. Mungas was negligent, even though it retained a respected expert who believed that he was. The record does not reveal the reasons for Ethicon's decision. It is possible that Ethicon considered the views of Dr. Olcott and disagreed with him or concluded that a jury would not find his opinion persuasive. It is also possible that Ethicon made this decision simply to protect its good will among its customers, Montana surgeons. But

whatever the reason for its decision, there can be no doubt that Dr. Mungas' technique could have caused the suture to open without rising to the level of negligence. Thus, as a matter of science, common sense and business practice, Ethicon's contentions were perfectly proper.

Because Ethicon did not contend that Dr. Mungas was negligent, it did not abuse the discovery process by not revealing Dr. Olcott's opinion in response to contention interrogatories. Ethicon was never warned that its responses were improper, it never defaulted on any of its promises, it was never ordered to answer the interrogatories any differently than it did, and it never violated any order. Because Ethicon could have prevailed at trial without claiming or proving that Dr. Mungas was negligent, the entry of a default judgment, based on responses that had not been previously challenged, was fundamentally unjust and violated Ethicon's due process rights.

The basic harm created by this decision, however, is not limited to the $2.3 million default judgment imposed as a sanction against Ethicon. It is far more reaching and will prove more costly to pharmaceutical and medical device manufacturers, as well as to the American consuming public. Armed with this precedent, plaintiffs will seek to shift their burden of proof vis-a-vis defendant pharmaceutical manufacturers and physicians, forcing such defendants to prove the plaintiff's case against each other. Faced with this precedent, pharmaceutical manufacturers and physicians will be compelled to pursue claims against each other in order to avoid sanctions, ignoring the fact that unsuccessful medical procedures do not necessarily result from negligent medical care or defective medical products. As a consequence,

pharmaceutical and medical device product liability litigation will become an even more complicated and expensive process for the parties and the courts.

At a time when our country actively addresses universal health coverage and the need to reduce the costs of medical care, *see* Adam Clymer, *Debate is Begun on Mitchell Plan for Health Care,* N. Y. Times, August 10, 1994 at A1, it is ironic that the inevitable result of the trial court's decision will be to increase medical costs. The prudent defense strategy for a pharmaceutical manufacturer, sued together with a treating physician, will now be to pursue all potential claims against the codefendant physician, regardless of whether it makes tactical or business sense and regardless of the increased defense costs thereby imposed on both the manufacturer and the physician. Unfortunately, basic principles of economics dictate that these defense costs will ultimately be passed on to the purchasing public by the manufacturer as well as the doctor. *See generally* Louis Lasanga, *The Chilling Effect of Product Liability on New Drug Development, in* The Liability Maze: The Impact of Liability Law on Safety and Innovation 334, 335 (Peter W. Huber, et al. eds., 1991).

The decision below denied Ethicon the right to assert meritorious defenses without any basis for presuming that Ethicon had none, and it deprived Ethicon of its rights under the Fifth and Fourteenth Amendments to the United States Constitution. The decision below will also impose costly burdens on defendant manufacturers and physicians, as well as on the people who benefit from the medical products and care provided by such defendants.

CONCLUSION

For the foregoing reasons, American Cyanamid Co, Boots Pharmaceuticals, Bristol-Myers Squibb, CIBA-GEIGY Corporation, Hoffmann-LaRoche Inc., Pfizer Inc., the Pharmaceutical Research and Manufacturers of America, Rhone-Poulenc Rorer Inc., Schering-Plough Corporation, The Upjohn Co. and Warner-Lambert Company all support Ethicon, Inc.'s Petition for a Writ of Certiorari to the Supreme Court of the State of Montana.

Respectfully submitted,

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